



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2016-D-4318]**

### **Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities; Guidance for Industry; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Food and Drug Administration (FDA or the Agency) is announcing the availability of a guidance for industry entitled “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” This guidance sets forth FDA’s policy regarding compounding and repackaging of radiopharmaceuticals for human use by State-licensed nuclear pharmacies, Federal facilities, and other entities that hold a radioactive materials (RAM) license for medical use issued by the Nuclear Regulatory Commission (NRC) or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackage radiopharmaceuticals.

**DATES:** The announcement of the guidance is published in the *Federal Register* on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

*Instructions:* All submissions received must include the Docket No. FDA-2016-D-4318 for “Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities.” Received comments will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about

FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:** Sara Rothman, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 301-796-3110.

**SUPPLEMENTARY INFORMATION:**

I. Background

FDA is announcing the availability of a guidance for industry entitled "Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities." Under current law, radiopharmaceuticals that are compounded by entities that are not registered with FDA as outsourcing facilities, and radiopharmaceuticals that

are repackaged, are subject to all applicable provisions of the FD&C Act related to the production of drugs. Because Congress explicitly excluded radiopharmaceuticals from section 503A of the FD&C Act (21 U.S.C. 353a) (see section 503A(d)(2)),<sup>1</sup> compounded radiopharmaceuticals are not eligible for the exemptions under section 503A from section 505 (21 U.S.C. 355) (concerning new drug approval requirements), section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning labeling with adequate directions for use), and section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements). In addition, the FD&C Act does not provide an exemption for repackaged radiopharmaceuticals.

FDA is issuing this guidance to describe the conditions under which the Agency generally does not intend to take action for violations of sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act when a State-licensed nuclear pharmacy, Federal facility, or other facility that is not an outsourcing facility and that holds a RAM license for medical use issued by the NRC or by an Agreement State compounds or repackages radiopharmaceuticals for human use.

Elsewhere in this issue of the *Federal Register*, FDA has announced the availability of a separate guidance document concerning compounding and repackaging of radiopharmaceuticals by outsourcing facilities entitled “Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities.”

In the *Federal Register* of December 29, 2016 (81 FR 96011), FDA issued a notice announcing the availability of the draft version of this guidance. The comment period on the draft guidance ended on February 27, 2017. FDA received comments on the draft guidance. In

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<sup>1</sup> Section 503A of the FD&C Act describes the conditions that must be met for drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to qualify for exemptions from sections 505, 502(f)(1), and 501(a)(2)(B) of the FD&C Act. Section 503A(d)(2) of the FD&C Act states that “this section shall not apply to . . . radiopharmaceuticals.”

response to received comments or on its own initiative, FDA made several changes that are reflected in this final guidance. For example, in response to requests in comments for clarification regarding the beyond-use-date, FDA added a recommendation that sterile radiopharmaceuticals should be compounded in compliance with USP Chapter <797>. In addition, to address questions raised in comments, FDA clarified the applicability of this guidance to various settings in which radiopharmaceuticals are administered, such as nuclear medicine departments and imaging centers, by clarifying that the policies in the guidance apply to facilities that are not outsourcing facilities and that hold a RAM license for medical use issued by the NRC or by an Agreement State.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

## II. Paperwork Reduction Act of 1995

This guidance contains collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information have been approved under OMB control number 0910-0858.

## III. Electronic Access

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm> or <https://www.regulations.gov>.

Dated: September 20, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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